

### REMARKS

In the first office action, the examiner requires restriction to one of the following inventions under 35 U.S.C. §121:

Group I: Claims 1-27, drawn to a method for providing long term pain management, classified in class 604, subclass 512;  
and

Group II: Claims 28-29, drawn to a surgical needle for use in inserting a catheter, classified in class 604, subclass 187.

The examiner requires election of one group for prosecution on the merits, even if restriction is traversed, in accordance with 37 C.F.R. §1.143.

### Election and Traversal

Applicant provisionally elects Group I (claims 1-27, and added claims 30 and 31, drawn to a method for providing long term pain management, classified in class 604, subclass 512) for immediate prosecution, and respectfully traverses the restriction requirement, requesting reconsideration and withdrawal of same.

Applicant makes no representation by this election regarding the possible existence of multiple independent and/or distinct inventions among the claims of record. Pursuant to 37 C.F.R. § 1.143, the request for reconsideration is made to preserve applicant's right of petition should the examiner reassert restriction.

**Examiner's requirement of demonstrating extra burden on the PTO has not been satisfied as Examiner has failed to satisfy "separate status in the art" or "separate classification"**

Even if two or more claim groupings are independent or distinct as claimed, there must also be a serious burden on the examiner to require restriction. M.P.E.P. §803. If the search and examination of the entire application can be made without serious burden, the examiner must examine the application on its merits, in its entirety, even though the application includes claims to distinct and/or independent inventions. M.P.E.P. §803. The examiner has failed to show, in the present case, that examining both groups on the merits would present a serious burden.

In the office action, the examiner fails to show, or even mention, that a search and examination of the entire application would present a serious burden. The examiner, therefore, has not satisfied the criteria necessary for requiring restriction in this application.

Indeed, M.P.E.P. §803 requires, for proper restriction:

**CRITERIA FOR RESTRICTION BETWEEN  
PATENTABLY DISTINCT INVENTIONS**

There are two criteria for a proper requirement for restriction between patentably distinct inventions:

(A) The inventions must be independent (see MPEP § 802.01, § 806.04, § 808.01) or distinct as claimed (see MPEP § 806.05 - § 806.05(i)); *and*

(B) There must be a serious burden on the examiner if restriction is required (see MPEP § 803.02, § 806.04(a) - § 806.04(i), § 808.01(a), and § 808.02).

Since the examiner has failed, in the office action, to even address the second criteria (part B), the examiner has failed to satisfy his burden to show that restriction is proper.

Further, even if the examiner were to conclude that search and examination of the entire application would create a serious burden, which he has not, M.P.E.P. §803 further requires that the examiner provide reasons and/or examples to support the conclusions.

M.P.E.P. §803 does provide that, “for purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation of separate classification, or separate status in the art, or a different field of search as defined in MPEP §808.02.” The examiner, however, also fails to satisfy this *prima facie* showing.

**Examiner has failed to show “separate classification,” for failure to show “separate field of search”**

In concluding that restriction is proper, and therefore required, the examiner states in the office action: “because these inventions are distinct for the reasons given above [i.e., that the method does not require use of the surgical needle] and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.” The examiner has failed, however, to satisfy his burden of showing separate classification.

*(Note: applicant assumes that the examiner, in the statement quoted above, relies on different classification, and not on separate status in the art, in concluding that restriction is proper, since separate status in the art, as referenced below in M.P.E.P. §808.02(B), requires that the groups be classified together, and requires that an explanation indicating a recognition of separate inventive effort by inventors be provided. In the present case, the examiner states that the groups are classified differently, and does not mention any explanation indicating recognition of separate inventive effort by inventors).*

In accordance with M.P.E.P. §806.05(c), the examiner's requirement in satisfying separate classification is articulated in M.P.E.P. §808.02 **Related Inventions**:

Where the related inventions as claimed are shown to be distinct under the criteria of MPEP § 806.05(c) - § 806.05(i), **the examiner**, in order to establish reasons for insisting upon restriction, **must show** by appropriate explanation one of the following:

- (A) **Separate classification thereof:** This shows that each distinct subject has attained recognition in the art as a separate subject for inventive effort, *and* also a separate field of search. Patents need not be cited to show separate classification.
- (B) **A separate status in the art when they are classifiable together:** Even though they are classified together, each subject can be shown to have formed a separate subject for inventive effort when an explanation indicates a recognition of separate inventive effort by inventors. Separate status in the art may be shown by citing patents which are evidence of such separate status, and also of a separate field of search.
- (C) **A different field of search:** Where it is necessary to search for one of the distinct subjects in places where no pertinent art to the other subject exists, a different field of search is shown, even though the two are classified together. The indicated different field of search must in fact be pertinent to the type of subject matter covered by the claims. Patents need not be cited to show different fields of search.

The examiner, in his above-quoted conclusion, has failed to show separate field of search, as required by M.P.E.P. §808.02(A). The examiner, in requiring restriction, has failed to even mention separate field of search. Accordingly, the examiner has failed to satisfy his burden in requiring restriction in the present application.

#### **Linking Claim**

Applicant notes that added claim 30 is a linking claim, linking non-elected product claim 29 to the elected method claim 1, as defined in M.P.E.P. § 821.04, and that added

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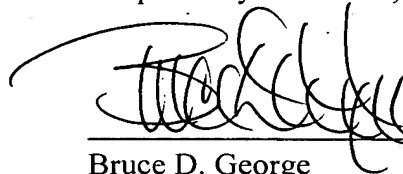
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claims 30 and 31 must be examined with the elected invention. If ultimately allowed, rejoinder is required. M.P.E.P. § 809.04.

### Conclusion

For the foregoing reasons, and particularly because the examiner has failed to satisfy his burden of showing extra burden on the PTO through separate classification and separate field of search, applicant respectfully requests reconsideration and withdraw of the restriction requirement. Notification that the restriction requirement has been reconsidered and withdrawn is respectfully solicited.

Respectfully submitted,



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